highly effective and safe primary treatment modality. Initial thrombosis rates exceeded 90% and no serious complications were observed in this series despite a high rate of concomitant antiplatelet and antithrombotic therapy.

TCT-404

Efficacy and Safety of Total Percutaneous Femoral Closure Following Stent Graft Implantation Using Preclose Technique

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Background: The preclose technique with the 6 F Proglide for complete percutaneous endovascular aortic repair have not been sufficiently evaluated. We investigated the efficacy and safety of the preclose technique in a sufficient and large cases.
Methods: The medical records of 367 patients with 599 preclose techniques for various aortic repairs were reviewed. Procedural success was defined as hemostasis achieved by the preclose technique, without the need for surgical or endovascular procedures. Access related major adverse event (ARMAE)s were considered as those event, such as infection, bleeding, new onset ischemia of the lower leg, hematoma, pseudoaneurysm, arteriovenous fistula, embolization, laceration, femoral artery thrombosis, nerve injury, or death by access site injury.
Results: Procedural success was achieved in 359 of 367 patients (97.8%) and 591 of 599 left or right femoral sites (98.7%). All cases of procedural failure were treated by immediate surgical repair of femoral arteries. The preclose technique was more successful in the smaller sheath. ARMAEs developed in 25 of 367 patients (6.8%) and 26 of 599 sites (4.3%). Access site hematoma was the most frequent adverse events (16 of 367 patients (4.4%) and 17 of 599 sites (2.8%)), followed by puncture site pseudoaneurysm (7 of 367 patients (1.9%) and 7 of 599 sites (1.2%)). Bleeding after arterial closure occurred in 6 of 367 patients (1.6%) and 6 of 599 sites (1.0%). In 2 of 367 patients (0.5%), there was an infection at the puncture site. There were two cases of distal embolization, one case of acute femoral thrombosis, and one case of a vascular laceration at the puncture site. There were no access site related nerve injury, arteriovenous fistula or death complicated by access site.
Conclusions: The preclose technique can be used to achieve hemostasis for stent graft procedure successfully, with a high rate of procedural success and an acceptable rate of adverse event, the most common being puncture site hematoma formation.

TCT-405

Transradial approach decreases in-hospital mortality in patients with cardiogenic shock. A single-center experience

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Background: Transradial approach (TRA) in percutaneous coronary intervention (PCI) has increased over the past few years. Its use has been shown to decrease mortality compared with the transfemoral approach (TFA) in patients with acute coronary syndrome (ACS). Comparative studies have systematically excluded patients with cardiogenic shock (CS).
Methods: We carried out a prospective, observational registry study of consecutive patients undergoing emergent revascularization between February 2007 and January 2012. An analysis of the clinical evolution of patients with CS during hospitalization was performed according to the approach used in the PCI.
Results: Of 1,400 emergency procedures, 122 had CS, 80 underwent PCI by TRA (65.6%) and 42 by TFA (34.3%). The main reason for choosing TFA was the absence of radial pulse (54.9%). Mortality (64.3% vs. 32.5%, p=0.001), serious access site complications (11.9% vs. 2.5%, p=0.03) and MACE (combination of death, infarction, stroke, serious bleeding, and postanoxemic encephalopathy) (73.8% vs. 43.8%, p=0.001) were greater in TFA patients. In the multivariate analysis, TRA was a predictor of mortality (OR 0.39[0.15-0.97]); other predictive factors were age≥75 (3.47[1.35-8.92]), previous treatment with diuretics (3.67[1.21-11.12]) and the success of the procedure (0.08[0.02-0.24]).
Conclusions: In centers with experience, TRA approach for PCI is possible and safe in patients with CS in up to two thirds of the patients. The main cause that prevented the use of TRA was the absence of radial pulse. In the multivariate analysis, TRA was associated with a lower risk of mortality.

TCT-406

Trans-radial balloon aortic valvuloplasty

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Background: Ballooon aortic valvulplasty can be useful for palliation of symptoms in pts not eligible for surgical or transcatheter aortic vaalve replacement, or a a bridge to AVR. Occassionally transfemoral access is impossible or challenging, due to vascular disease or morbid obesity. We present our experience with trasnradial access for balloon aortic valvulplasty in pts not candidates for transfemoral approach.
Methods: 5 pts presented with critical aortic stenosis without femoral access. Transradial access was successfully obtained in all pts. In 1 pt a vascular loop prompted a change from the right to the left radial approach - the others were done via right radial access. Internal jugular venous access was used for PA catheter and pacing. After crossing the aortic valve using 6Fr amplatz 1 catheter with straight wire, and changing out for a dual lumen pigtail. Over an exchange length wire, the 6 Fr sheath was excheanged for an 8 Fr, and a 22 mm Tyshack balloon was advanced across the aortic valve and dilated during rapid pacing. Due to inadequate hemodynamics, in 1 case the 8 Fr sheath was exchanged for a 9 Fr, and a 25 mm Tyshack balloon used.
Results: In 4 of 5 pts aortic valvuloplasty was attempted and successfully performed. In 1 pt with morbid orbesity vigourous diuresis was instead successful in treating his CHF and one year later he underwent successful surgical AVR. 1 of the pts with successful balloon valvuplasty had occlusive lower extremity arterial disease and need for warfarin for a mechanical mitral valve, the others had morbid obesity (mean weight 168 kg). All pts had hemodynamic improvement, mean AV gradient decreased from 47 to 36 (23%), and AVA increased from 0.85 to 1.1 (29% increase). The pt with 9 Fr sheath had small amount of tissue removed with removal of the 9 Fr sheath, but no clinical complications in any pt.
Conclusions: Radial artery access is a feasible option for the performance of balloon aortic valvuloplasty in patients with poor femoral artery access.

TCT-407

Vascular Hemostasis Devices: Food And Drug Administration Perspective On Reported Risks

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Background: Vascular Hemostasis Devices (VHD) are regulated by FDA as high-risk Class III medical devices requiring Pre-Market Approval (PMA). First approved in 1995, these devices have evolved and been broadly adopted for hemostasis use, with current use estimates up to 50% of all coronary procedures. FDA databases were searched to provide a regulatory summary and device profile overview.
Methods: The PMA, Adverse Event, Recall, Registration and Inspection databases were searched using the device product code and years 2007 through 2011. Statistical testing used t-test and X2, as appropriate for proportions or means, with significance level of 0.05.
Results: The FDA registration and listing database identified 8 different manufacturers and 11 different devices. FDA approval of the 11 devices occurred from 1995 through 2011. 10 of the 11 listed devices are made in the US by US manufacturers. Two manufacturers represented 95% of the VHDs reported in adverse events. The number of annual adverse events reports increased 300% from 1,402 in 2007 to 4,243 in 2011, with a five year total of 14,120 reports received. Geographically, 72% of the adverse events occurred in the US and 27% in 53 other countries. Females were disproportionately represented (p< 0.001, 44% vs. 34% expected). Patient age ranged from 4 to 98 years, with women found to be older than men (65.8 vs. 64.7, p<0.01). A total of 164 reports for death as the patient outcome were received. For women, deaths were present in 3.38% of the reports compared to 1.28% for men (p<0.001, odds ratio 2.7 [CI 1.908, 3.802]). During the timeframe there was one US recall for a compromised sterility issue and one foreign recall for increased failure rates. US Manufacturer and contractor inspections included four cases of FDA citations requiring actions.
Conclusions: Reasons women experience higher risks are not known but appear to persist despite product experience and design changes. More research on gender differences and device design is recommended. Increased overall numbers of VHD adverse event reports to FDA likely parallels temporal increases in use. Limitations relate to missing data for patient age and gender, and known underreporting of adverse events.

TCT-408

Sheathless Guide Catheters in complex Transradial PCI. A Single Center Experience

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Background: The Sheathless Guiding Catheter (SGC) (Sheathless Eaucath, Asahi Intecc Co, Japan) has Hydrophilic coatings that enhances catheter tractability through tortuous vessels and allow dealing with radial spasm and performing Percutaneous Coronary Intervention (PCI) by radial approach in complex cases. We reported our experience in 91 patients (pts) with complex transradial approach in whom SGC was used to avoid femoral cross over to complete the procedure.

Methods: Of 1918 PCI (1623 pts, aged 66 ± 4 years old; 65% males) performed in our catheterization laboratory from January the 1st 2011 to January the 31st 2012, the 70% (1342) were performed via radial and 576 (30%) via femoral (187 cross over from radial, 324 due to operator criteria 65 for no appropriate Sheathless shape available) and 156 PCI (142 pts) initially scheduled via femoral were rescue to radial using SGC. Reasons for SGC use were: moderate to severe radial spasm in 48, tortuosity and/or subclavian elongation in 36, proximal radial take-off in 12, insufficient backup or difficulties to coronary engage in 23 and 37 by expected mismatch between radial artery and catheter needed for PCI.
Results: A total of 164 SGC were employed (98 (60%) of 6.5 Fr), being Super Power Backup (68%) the most common used followed by Amplatz left (21%). Successful rate was 100%. 105 left and 51 right coronary were engaged with SGC. There were 5 left main and 2 right coronary ostium (4,5%) iatrogenic dissections (all resolved with stent implantation). In 13 (8.3 %) cases there was an insufficient backup due to backward slip of the catheter at radial insertion point in the wrist that led to the need of active fixation of the catheter at that point.
Conclusions: The larger inner diameter, hydrophilic coated and tractability of SGC allows performing complex transradial procedure with a high successful rate and low cross over rate. The risk of coronary ostiums dissection with SGC is not neegligible and manufacturers should consider diminishing catheter tip' stiffness. In complex procedures (chronic occlusions, rotablator, etc) active fixation at the wrist should be considered to avoid the backward slip of the catheter at the insertion point in the wrist.

TCT-409

Radial Access: Is There An Increased Risk Of Operator Radiation Exposure During A Right Versus Left Radial Approach?

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Background: The transradial approach (TRA) is widely being adopted as the preferred method of access for coronary angiography. Previous studies have demonstrated that access with the left radial approach (LRA) may have some advantages over the right radial approach (RRA) such as decreased tortuosity and better catheter support. Few studies have demonstrated a significant difference in the amount of fluoroscopy time (FT) and environmental radiation exposure, but little data exist showing direct radiation exposure to the operator when comparing these two approaches. The aim of this study is to determine weather there is a significant difference in direct radiation exposure to the operator when using a LRA versus a RRA.
Methods: A total of 60 consecutive patients were randomized to a LRA or RRA. Patients with arteriovenous fistulas, prior coronary bypass surgery, or ST-elevation myocardial infarcts were excluded. Radiation dosimeter badges (RDB) were strategically placed on the head, external thyroid and internal sternum for each operator. Individual variables, including FT, scenes, calculated radiation dose, Head RDB, External Thyroid RDB and Internal Sternum RDB, were independently compared between LRA and RRA using a two-sampled t-test.
Results: There was no significant difference in FT, scenes and calculated radiation dose between LRA and RRA. However, a comparison of the RDB reveals a significant difference in direct radiation exposure to the operators' external thyroid RDB (p=0.015) and a trend towards significance in the head RDB (p=0.070). There was no significant difference in the internal sternum RDB measurements. (Table 1)

Table 1

	LRA (n=31)	RRA (n=29)	p-value
FT (min)	13.1±8.9	11.5±8.2	0.483
Scenes	15.1 ±9	16.2 ±10	0.659
Calculated Radiation Dose (MGy)	1634 ±921	1853 ±1545	0.512
Head RDB (mRems)	12.5 ±9.3	17.7 ±12.6	0.070
External Thyroid (mRems)	19.1 ±15.0	33.0 ±26.9	0.015
Internal Sternum (mRems)	3.0 ±4.5	4.0 ±5.3	0.462

Conclusions: There is a statistically significant increased risk of operator radiation exposure seen in the external thyroid RDB, and a trend towards significance in the head RDB, during a right radial approach.

TCT-410

Arteriotomy Location Guided by Fluoroscopy Plus Real-time Ultrasound: In Defense of the Femoral Approach

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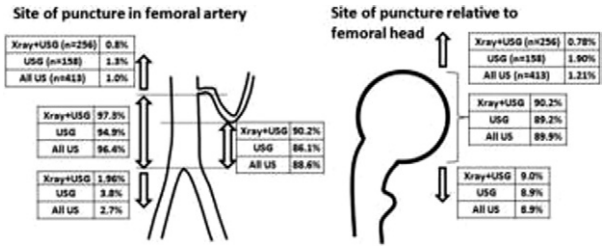
Background: Vascular complications are increased by puncture above or below the common femoral artery (CFA). The FAUST study showed that real-time ultrasound guidance (USG) modestly increased accuracy over fluoroscopic guidance (86.4% vs 83.3% CFA punctures) and decreased vascular complications. We hypothesized that USG accuracy could be improved.
Methods: 416 consecutive femoral sheath arteriograms were analyzed by a blinded reviewer. Procedures were performed with USG alone or with fluoroscopic femoral landmarks + USG (Xray+USG) by a single operator with USG experience. A micropuncture system and ultrasound probe needle guide were used. We recorded the site of arteriotomy in the femoral artery and also relative to the femoral head (FH), and the relation of the femoral bifurcation (FBi) to the FH.
Results: The puncture was in the CFA in 97.3% (Xray+USG; n=256) and 94.9% (USG; n=158; difference NS). The FBi was above the inferior border of the FH in 47.6% of studies, and above the middle of the FH in 4.1%.



Conclusions: Despite many high bifurcations, Xray+USG guidance permitted CFA puncture in 97.3% of catheterizations. The radial approach, pharmacologic improvements and other strategies have focused attention on the importance of reducing bleeding and vascular complications. Our series suggests that the Xray+USG technique may improve outcomes when the femoral approach is needed, as for large catheter interventions.

TCT-411

Use of Sheathless Guide Catheter with Transradial Percutaneous Coronary Intervention: Single Center Experience with 7853 Procedures

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Background: Sheathless guide catheter is a hydrophilic catheter without use of an introducer sheath so that it decreases stress to radial artery. Although transradial percutaneous coronary intervention (TRI) using a sheathless guide catheter (Sheathless TRI) associates potential limitations such as its procedural complexity or coronary ostial dissection due to its tip stiffness, any large number studies have not shown the data yet.
Methods: Our institution has utilized transradial approach as an initial system for more than ten years. Since we started to use sheathless TRI in 2004, with experiences and improvement of devices sheathless TRI is currently utilized in most TRIs including emergent cases, even in bifurcation or rotational atherectomy by using 7.5 Fr sheathless TRI. We retrospectively investigated the feasibility and safety of sheathless TRI, undertaken at our institution from January 2004 to December 2011.
Results: A total of 10293 PCIs was performed in this study period by 43 operators including beginners to specialists. TRI was performed in 8868 cases, consisting of 7853 cases (88.5%) of sheathless TRI and 1015 cases (11.5%) of TRI using a conventional sheath. In any cases other than chronic total occlusion procedural success, defined as successful revascularization without conversion to other guide catheter systems, was achieved in 98.9% of sheathless TRI and 98.0% of TRI using conventional sheath (p=0.018). Conversion from sheathless TRI to other system was occurred in 37 cases (0.47%) including 35 cases from sheathless TRI to TRI using conventional sheath and 2 cases from it to transfemoral approach. Coronary ostium dissection was occurred in 20 cases (0.23%) in all TRIs including 16 cases (0.20%) by sheathless TRI and 4 cases (0.39%) by TRI using conventional sheath (p=0.28), which were all bailed out by stent deployment resulting in procedural success. Critical arm ischemia requiring amputation or resulting in persistent paralysis was not seen in any cases.
Conclusions: Use of sheathless guide catheter via transradial artery is a feasible approach as an initial system for any interventionalists in any situations as long as transradial approach is permitted.

TCT-412

Diltiazem, verapamil or dinitrate isosorbid for prevention of radial artery spasm in percutaneous coronary intervention

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Background: Radial artery spasm (RAS) remains the major limitation of transradial approach for percutaneous coronary interventions (PCI). We have previously demonstrated efficacy of verapamil to reduce RAS but recently, supply problems have occurred and many cathlab have changed verapamil to another calcium channel blocker, diltiazem.

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